DEPARTMENT OF HEALTH & HUMAN SERVICES 9143948
New York District

Food & Drug Administration
158 - 15 Liberty Avenue
Jamaica, New York 11433-1034

WARNING LETTER

June 26, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED ***REF: NYK-2001-84***

Ivy Engel, M.D.
Supervising Radiologist / Lead Interpreting Physician
Nassau Health Care Corporation Mammography Center - ***MOBILE-Unit #1-Van***
Freeport Health Center (Processing)
460 North Main Street
Freeport, New York 11520 ***Facility ID: #201640***

Dear Dr. Engel:

Your facility was inspected on June 15th, 2001, by a representative of the Nassau County Department of Health, Office of Radiological Control Unit, acting on behalf of the U. S. Food & Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography operations at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography operations. These requirements help protect the health of women by assuring that a facility can perform quality mammography procedures.

The inspection revealed the following Level 1 noncompliance finding at your facility:

- ***Phantom QC records were missing for at least four (4) weeks for unit #1, Lorad Medical Systems, Inc., T350 for the MOBILE Unit #1-Van.***

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 noncompliance, because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography operations and services at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

There was also a Level 2 noncompliance finding that was listed on the inspection report provided at the close of the inspection. The Level 2 noncompliance finding was as follows:

- ***A performance verification test was not conducted after each move for MOBILE - Unit #1, Lorad Medical Systems, Inc., T350 for the MOBILE Unit #1-Van.***

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violation noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations; and
- Sample of records that demonstrate proper record keeping procedures.

Please submit your response to the above issues to the attention of Arthur S. Williams, Jr., Compliance Officer, U. S. Food & Drug Administration (FDA), 158 - 15 Liberty Avenue, Jamaica, New York 11433-1034, Tel.: (718)/662-5568.

Finally, you should understand there are many FDA requirements pertaining to mammography operations and procedures. This letter pertains only to the findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, U. S. Food & Drug Administration (FDA), P.O. Box 6057, Columbia, Maryland 21045-6057, Tel. (1-800/838-7715), or through the Internet at http://www.fda.gov.

Sincerely yours,

Timothy E. Hansen
Acting District Director
New York District